

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

_____)	MDL No. 2419
IN RE: NEW ENGLAND)	No. 1:13-md-02419-RWZ
COMPOUNDING PHARMACY, INC.)	
PRODUCTS LIABILITY LITIGATION)	
)	
THIS DOCUMENT RELATES TO:)	
ALL ACTIONS)	
_____)	

MEMORANDUM IN SUPPORT OF
COMMONWEALTH OF MASSACHUSETTS'
MOTION FOR A PROTECTIVE ORDER

The Commonwealth of Massachusetts (the “Commonwealth”) serves and files this memorandum in support of its accompanying motion for a protective order (motion).

The Tennessee Clinic Defendants served a third-party subpoena on the Commonwealth (specifically, on its agency the Board of Registration in Pharmacy) (the Board) dated March 18, 2015 (Doc #1735). The subpoena commanded the Commonwealth to produce nine (9) categories of documents related to New England Compounding Center (NECC) and a 2012 nationwide outbreak of fungal meningitis. It included a notice of a Rule 30(b)(6) deposition on eighteen (18) topics, and set the date for deposition for May 6, 2015. That date was tentatively extended by agreement to June 15, 2015 pending the production of documents. The Commonwealth sent a letter of objections dated April 8, 2015, and the parties have conferred several times since then.

Many of the subpoenaed documents were previously produced by the Commonwealth in response to subpoenas issued by a committee of the United States House of Representatives. No documents have been produced to date to the Tennessee Clinic Defendants, and they have filed a Notice of Postponement of Deposition (Doc #1961), but the Commonwealth will be producing copies of the previously-produced documents imminently, on a rolling basis. In preparing to

make production, counsel for the Commonwealth contacted the Office of the United States Attorney to ascertain whether the United States would have any concerns about the production of any of the documents or of Rule 30(b)(6) witnesses. During these discussions, members of the U.S. Attorney's Office for the District of Massachusetts apprised the Commonwealth that Rule 30(b)(6) testimony could interfere with the pending trial of the criminal action of *United States v. Cadden*, No. 1:14-cr-10363-RGS (D. Mass.). The U.S. Attorney's Office has made no objection to the Commonwealth's intended document production.

The Declaration of United States Attorney Carmen M. Ortiz on this matter is attached hereto as Exhibit A. As stated therein at ¶¶ 13-14, the deposition sought by the Tennessee Clinic Defendants relates to some of the same conduct that is in issue in the criminal case, which involves the deaths of at least 64 persons and the illness of 687 others throughout the country. The U.S. Attorney believes that the public interest requires that the ongoing investigation of NECC and the prosecution of the 14 defendants not be hindered by the Board's premature deposition testimony regarding its investigation, regulation and actions related to NECC prior to the meningitis outbreak. Such a deposition, prior to the trial of the criminal case, could require the participation of federal prosecutors in helping to prepare the testimony of the Board's witnesses, thereby distracting them from the preparation of the criminal case; could require the early disclosure of the elements of the government's case-in-chief; and could generate substantial pretrial publicity that might unnecessarily prejudice all parties' rights to a fair criminal trial before an impartial jury.

The Commonwealth's counsel have been informed that the United States has moved for a protective order as to a 30(b)(6) deposition subpoena served on the Food and Drug Administration (Doc #1838), also on the ground that such testimony might prejudice the criminal

case. It is believed that the Court's ruling on that motion could resolve the same question as to the timing of the Commonwealth's 30(b)(6) deposition. Commonwealth counsel have also been informed that the Court has called for briefing on the choice of law applicable to the civil cases against the Tennessee Clinic Defendants, and believe that a ruling adverse to the Tennessee Clinic Defendants on that question could eliminate or significantly narrow the scope of the proposed deposition.

For these reasons, and also for the reasons advanced by the United States in its motion for a protective order and its supporting exhibits (Doc #1838) and its supporting exhibits and memorandum, which the Commonwealth hereby adopts and incorporates by reference, the Commonwealth's motion should be allowed.

A proposed order is attached hereto as Exhibit B.

COMMONWEALTH OF MASSACHUSETTS
MAURA HEALEY, ATTORNEY GENERAL

s/ Ronald F. Kehoe

Ronald F. Kehoe, BBO # 264260
Special Assistant Attorney General
Michelle Kalka, BBO # 624897
Assistant Attorney General
Government Bureau/Trial Division
One Ashburton Place, Room 1813
Boston, MA 02108
(617) 727-2200, ext. 2776 (MK)
michelle.kalka@state.ma.us

Dated: June 16, 2015

EXHIBIT A --

**DECLARATION OF UNITED STATES
ATTORNEY CARMEN M. ORTIZ**

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND
COMPOUNDING PHARMACY,
INC., PRODUCTS LIABILITY
LITIGATION

Court No.: 13-md-2419-RWZ

DECLARATION OF UNITED STATES ATTORNEY CARMEN M. ORTIZ

Pursuant to Title 28, United States Code, Section 1746, I, Carmen M. Ortiz, declare as follows:

1. I am the United States Attorney for the District of Massachusetts, and have served in this position since 2009.

2. As United States Attorney, I lead the United States Attorney's Office ("USAO") and oversee the work of approximately 120 Assistant United States Attorneys ("AUSAs"). The USAO represents the United States in federal criminal and civil matters within the District of Massachusetts.

3. This declaration is based on my personal knowledge of the USAO's criminal investigation, and information supplied to me in my official capacity as the United States Attorney for the District of Massachusetts.

The NECC Criminal Investigation

4. Beginning in October 2012, the USAO commenced a criminal investigation of New England Compounding Pharmacy, Inc., doing business as New England Compounding Center ("NECC"). The criminal investigation was a result of the nationwide outbreak of fungal meningitis. The U.S. Centers for Disease Control and Prevention ("CDC") has reported that 751 patients in 20 states were diagnosed with a fungal infection after receiving injections of NECC's

methylprednisolone acetate. Of those 751 patients, the CDC reported that 64 patients in nine states died.

5. The NECC criminal investigation is one of the highest priorities of the USAO; in fact, it is one of the most significant federal prosecutions currently ongoing in the United States. The prosecution is led by a team of AUSAs in the USAO and attorneys from the Consumer Protection Branch of the Department of Justice (“DOJ”). The investigation is being conducted by the U.S. Food and Drug Administration’s Office of Criminal Investigations; the Federal Bureau of Investigation; the Department of Veterans Affairs, Office of Inspector General; the Department of Defense, Defense Criminal Investigative Service; and the United States Postal Inspection Service.

6. As part of the criminal investigation, AUSAs and law enforcement agents conducted a thorough review of NECC’s regulatory history, including its previous inspections by the United States Food and Drug Administration (“FDA”) and the Massachusetts Board of Registration in Pharmacy (“MABOP”), and NECC’s representations about its business to the FDA and the MABOP throughout its years of operation.

7. On December 16, 2014, a federal Grand Jury sitting in Massachusetts returned a 131-count indictment charging 14 owners, employees, and associates of NECC with a variety of criminal charges in United States v. Barry J. Cadden et al., 14-cr-10363-RGS. Barry J. Cadden (“Cadden”), NECC’s owner and head pharmacist at NECC, and Glenn A. Chin (“Chin”), NECC’s supervisory pharmacist, were charged with racketeering, in violation of Title 18, United States Code, Section 1962, based in part on twenty-five acts of second-degree murder in Florida, Indiana, Maryland, Michigan, North Carolina, Tennessee, and Virginia. Cadden and Chin face a maximum punishment of life imprisonment. The indictment also charges that Cadden, along

with four other defendants, conspired to defraud the FDA by purporting to operate NECC as a MABOP-regulated pharmacy, dispensing drugs pursuant to valid, patient-specific prescriptions, rather than as a drug manufacturer distributing drugs in bulk to customers and subject to heightened FDA oversight.

8. The 14 defendants in the criminal case were arraigned on December 17, 2014. Since that date, the USAO has provided the defense with approximately 8.8 million pages of discovery. No trial date is presently set. The prosecution team is actively engaged in extensive pretrial proceedings, including interviewing new witnesses, continuing to review and assess seized documents and evidence, preparing and producing discovery to the criminal defendants, and responding to filings in the criminal case. The USAO anticipates calling multiple MABOP witnesses at trial.

Interference with the Criminal Case

9. I am informed that on March 18, 2015, the MABOP was served with a notice of deposition and subpoena to testify pursuant to Federal Rules of Civil Procedure 30(b)(6) and 45 in connection with civil lawsuits filed against doctors and clinics in Tennessee (“Tennessee Clinic Defendants”) who administered NECC’s drugs to patients. As discussed below, I have been briefed regarding the deposition notice and documents subpoenaed.

10. The Tennessee Clinic Defendants seek a deponent and documents related to: (a) MABOP’s authority to investigate, inspect, regulate, and take action against NECC prior to the fungal meningitis outbreak; (b) MABOP’s investigation, inspections, regulation, and actions related to NECC prior to the fungal meningitis outbreak; (c) MABOP’s cooperation with the FDA prior to the fungal meningitis outbreak; (d) the information known by the MABOP about

NECC prior to the fungal meningitis outbreak; and (e) MABOP's investigation, inspection of, and action against NECC following the fungal meningitis outbreak.

11. Compliance with the Tennessee Clinic Defendants' notice of deposition to the MABOP would interfere with the ongoing criminal case, United States v. Barry J. Cadden et al., 14-cr-10363-RGS. Accordingly, I request that the Court stay the Tennessee Clinic Defendants' deposition request to the MABOP pending resolution of the criminal case. As outlined below, a stay protects the public's interest in achieving justice in the criminal case, preserves the integrity of the criminal case, protects the rights of the criminal defendants, and does not unduly prejudice the civil litigants.

12. The criminal activity charged in the criminal case resulted in the deaths of at least 64 individuals and the suffering of more than 687 others. The public deserves a criminal prosecution of the defendants unaffected by civil litigation focused on identical events. The public's interest in a just resolution of the criminal case is and should be paramount. This is particularly true given the fact that the two lead criminal defendants face potential punishments of life imprisonment for their actions.

13. The deposition sought by the Tennessee Clinic Defendants relates to some, if not much, of the same conduct at issue in the criminal prosecution, that is, the MABOP's authority, inspection history, and post-outbreak inspection and investigation of NECC. As currently requested, the deposition, pursuant to Fed. R. Civ. P. 30(b)(6), could involve depositions of more than one MABOP witness, given the broad topics and subject areas for which a deponent is sought, and these depositions would be given on behalf of the MABOP. A compelled deposition of one or more MABOP witnesses before the criminal trial would unfairly and unduly burden the USAO's continuing investigation of NECC and the criminal prosecution of the 14 defendants.

Because the MABOP deposition(s) in this civil matter would be available for use in the criminal matter as prior statements or admissions, the USAO's prosecution team would need to be involved in preparing the MABOP deposition witness(es) so that the team is aware of and understands the details of the witness(es)' testimony and how the testimony would relate to presentation of the government's case in the criminal proceeding. The USAO's involvement would also be necessary to ensure the completeness and accuracy of each witness's testimony, thereby reducing the appearance of inconsistencies from one proceeding to the next. But this participation would, in turn, have several burdensome effects on the criminal prosecution. It would interfere with the prosecution team's work in the criminal case, including interviewing new witnesses, reviewing seized documents and evidence, preparing and producing discovery, and conducting pretrial litigation, at a crucial stage of the case. It would also force the USAO now, months before the criminal trial, to prepare its trial strategy in the criminal case and the role and expected testimony of the MABOP witnesses in that strategic plan. Such preparation now would be difficult as a substantive matter, given the ongoing case development efforts noted in Paragraph 8 above. The deposition(s) would also prematurely and broadly disclose essential elements of the government's case-in-chief, allowing the criminal defendants to tailor defenses to fit the anticipated proof.

14. Furthermore, conducting a deposition of one or more MABOP witnesses now could generate substantial pretrial publicity that could affect the rights of the 14 criminal defendants to a fair trial. The fungal meningitis outbreak was an unprecedented public health crisis, and the USAO's criminal investigation has generated substantial coverage in both the national and local media for more than two years. It is my understanding that the Tennessee Clinic Defendants could potentially use the MABOP deposition testimony in more than 140

individual lawsuits against them. In a high-profile matter such as this, it is likely that such widespread use of the deposition testimony will result in leaks and disclosures of the testimony, in whole or part, to the media, inadvertently or otherwise. Premature disclosure about the government's case, including potential witnesses' testimony or details regarding the nature of evidence seized through search warrants, could affect the ability to seat a fair and impartial jury in the criminal case. While a protective order imposing appropriate confidentiality restrictions with respect to the content of the deposition(s), to the extent such restrictions were scrupulously implemented and followed, could potentially address such concerns, it would not eliminate the unfair burden and prejudice to the government in its prosecution of the criminal case otherwise set out in this declaration.

15. On the other hand, staying the MABOP deposition(s) until after the criminal trial would both reduce the burden on the MABOP witness(es) and produce some efficiencies in these civil cases because testimony by MABOP witnesses in the criminal trial could be used later in the Tennessee Clinic Defendants' civil litigation. As stated above, the USAO anticipates calling multiple MABOP witnesses in the criminal trial. Much of the testimony sought by the Tennessee Clinic Defendants will be elicited in the criminal case during the government's case-in-chief. Therefore, postponing the deposition(s) until after the criminal case has concluded is a more efficient use of MABOP resources than having parallel duplicative proceedings covering the same topics. Further, following the conclusion of the criminal trial, the Tennessee Clinic Defendants may find they no longer need a deposition from the MABOP at all, or instead may need only a more limited deposition focusing on a narrower set of topics.

I declare under penalty of perjury that the foregoing is true and accurate to the best of my knowledge, information, and belief.

Executed on June 15, 2015.

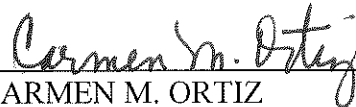

CARMEN M. ORTIZ
UNITED STATES ATTORNEY

EXHIBIT B --

PROPOSED ORDER

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

_____)	MDL No. 2419
IN RE: NEW ENGLAND)	No. 1:13-md-02419-RWZ
COMPOUNDING PHARMACY, INC.)	
PRODUCTS LIABILITY LITIGATION)	
)	
THIS DOCUMENT RELATES TO:)	
ALL ACTIONS)	
_____)	

[PROPOSED] ORDER

Upon the motion of the Commonwealth of Massachusetts for a protective order, the materials submitted in support of said motion and in opposition thereto, and good cause having been shown, it is hereby ordered as follows:

1. The said motion is granted.
2. The Commonwealth shall not be required to produce any witness for deposition under the subpoena dated March 18, 2015 from Tennessee Clinic Defendants to the Commonwealth's Board of Registration in Pharmacy and its Department of Public Health until 30 days after the completion of the trial in *United States v. Cadden*, No. 1:14-cr-10363-RGS (D. Mass.) or the entry of guilty pleas by all defendants in that action.

Dated _____

Jennifer C. Boal
Chief U.S. Magistrate Judge